CURRENT STATUS OF ALL CLAIMS IN THE APPLICATION

What is claimed is:

1. (Withdrawn)

2. (Withdrawn)

3. (Withdrawn)

4. (Withdrawn)

5. (Withdrawn)

6. (Withdrawn)

7. (Withdrawn)

8. (Withdrawn)

9. (Withdrawn)

10. (Withdrawn)

11. (Withdrawn)

12. (Withdrawn)

13. (Withdrawn)

14. (Withdrawn)

15. (Amended) A method for forming densified particles from a particulate pharmaceutical preparation, comprising compacting the preparation in a press to provide a compacted pharmaceutical preparation and size-reducing the compacted preparation into densified particles of suitable size and density for transdermal delivery thereof by needleless injection.

16. (Original) A method according to claim 15, wherein the suitable size is in the range of about 0.1 to 150 μm mean diameter.

17. (Original) A method according to claim 16, wherein the suitable size is in the range of about 20 to 60 μm mean diameter.

18. (Original) A method according to claim 15, wherein the densified particles have a particle density in the range of about 0.5 to 3.0 g/cm^3.

19. (Original) A method according to claim 18, wherein the particle density is in the range of about 0.8 to 1.5 g/cm^3.

20. (Original) A method according to claim 15, wherein the particulate pharmaceutical preparation is a lyophilized or spray-dried composition.

21. (Original) A method according to claim 15, wherein compacting is carried out in a press at about 1,000 to 24,000 pounds per square inch.

22. (Original) A method according to claim 21, wherein compacting is carried out under vacuum.

23. (Original) A method according to claim 15, wherein compacting is carried out without heating or shear.

24. (Previously Amended) A method according to claim 15, wherein size reducing of the compacted material is carried out by milling, sieving, or a combination of milling and sieving.

25. (Previously Amended) A method according to claim 15, wherein the method further comprises selecting densified particles by size classification.

26. (Previously Amended) A method according to claim 25, wherein the size classification of the densified particles is carried out by sieving or cyclone separation.

27. (Original) A method according to claim 15, wherein the particulate pharmaceutical preparation is a preparation of a peptide or protein.

28. (Original) A method according to claim 15, wherein the particulate pharmaceutical preparation is a preparation of a gene construct.

29. (Amended) A densified particulate pharmaceutical composition formed from a lyophilized or spray-dried pharmaceutical preparation by compacting the preparation in a press, said densified composition having an average particle size in the range of about 0.1 to 250 μm mean diameter and a particle density in the range of 0.1 to 25 g/cm^3.

30. (Original) A composition according to claim 29, wherein the lyophilized or spray-dried pharmaceutical preparation is a heat-sensitive biopharmaceutical preparation.

31. (Original) A composition according to claim 29, wherein the lyophilized or spray-dried pharmaceutical preparation is a preparation of a peptide or protein.

32. (Original) A composition according to claim 29, wherein the particulate pharmaceutical preparation is a preparation of a gene construct.

33. (Original) A composition according to claim 29, wherein the particle size is in the range of about 0.1 to 150 μm mean diameter.

34. (Original) A composition according to claim 33, wherein the particle size is in the range of about 20 to 60 μm mean diameter.

35. (Original) A composition according to claim 29, wherein the particle density is in the range of about 0.5 to 3.0 g/cm^3.

36. (Original) A composition according to claim 35, wherein the particle density is in the range of about 0.8 to 1.5 g/cm^3.

37. (Amended) A compacted particulate pharmaceutical composition formed by compacting a porous pharmaceutical preparation in a press, said compacted composition having an average particle size in the range of 0.1 to 250 μm mean diameter and a particle density in the range of 0.1 to 25 g/cm^3.

38. (Original) Particles of a suitable size and density for transdermal delivery by needleless injection, consisting of a gene construct and a pharmaceutically acceptable excipient.

39. (Original) A unit-dosage container for a needleless syringe comprising a compacted particulate pharmaceutical preparation according to claim 37.

40. (Previously Amended) A method of delivering a selected pharmaceutical agent to a vertebrate subject, said method comprising providing a compacted particulate pharmaceutical preparation according to claim 37, said preparation comprising the pharmaceutical agent, and delivering the preparation to a target tissue or cell of the vertebrate subject by needleless syringe.